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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,689	06/20/2003	Yu Ryang Pyun	LEELE81.001C1	6861

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,689

Applicant(s)

PYUN ET AL.

Examiner

Kagnew H Gebreyesus

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-12 and 16-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 13-15 and 17-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-12 and 16-30 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Applicant's election without traverse dated on Dec 27, 2004 is acknowledged.

1. Newly submitted claims 24 and 25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 24 and 25 depend on claim 17 which is part of a non-elected group.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24 and 25 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 8-12, 16 and new claims 26-30 are under consideration and are present for examination. Claims 1-7, 13-15 and claims 17-25 are withdrawn as non-elected claims.

Claim Objections

1. Claim 16 is objected to because of the following informalities: On line 5, the word isomerase is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. These claims 8, 9 and 16 are directed to a genus of arabinose isomerases isolated from *Thermotoga neapolitana*. The specification teaches the function and structure of only a single representative species of such enzyme from *Thermotoga neapolitana* of SEQ ID NO: 4.

Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being an arabinose isomerase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

Claims 8, 9 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide of SEQ ID NO: 3 encoding the arabinose isomerase polypeptide of SEQ ID NO: 4, does not reasonably provide enablement for any polynucleotide sequence encoding any derivative of an arabinose isomerase (SEQ ID NO: 4) from *Thermotoga neapolitana*. A nucleotide derived from an arabinose isomerase encompasses fragments, homologues, variants etc. of the specific isomerase of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 8, 9 and 16 are so broad as to encompass any enzyme comprising any arabinose isomerase derived from the specific sequence of SEQ ID NO: 3 encoding the specific arabinose

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isomerase polypeptide of SEQ ID NO: 4 from *Thermotoga neapolitana*. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of arabinose isomerase broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one arabinose isomerase from *Thermotoga neapolitana*.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all derived polypeptide sequences e.g. modifications of arabinose isomerase, fragments of arabinose isomerase which are derivatives of the arabinose isomerase of SEQ ID NO: 4 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting arabinose isomerase activity; (B) the general tolerance of arabinose isomerase

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to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any arabinose isomerase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including enzyme name with an enormous number of amino acid modifications of the enzyme name of SEQ ID NOS: 6 and 8. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of enzyme genes having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Does a derivative imply a homologue, fragment, variant etc. or does it point to a specific sequence? Clarification is required to decipher the scope of the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 8-12, 16, 26-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Hanson et. al. (US 20030129710A1). Hanson et. al. teach a novel thermostable isomerase and uses thereof of the enzyme which is 100% identical to the sequence disclosed by applicants (SEQ ID NO: 4).

8. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion:

No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. An arabinose isomerase from *Thermotoga maritima* that shows 96% sequence identity to SEQ ID NO: 3, applicants sequence of the arabinose isomerase from *Thermotoga neapolitana* was disclosed by Nelson K. E. et al. ("Evidence for lateral gene transfer between archaea and bacteria from genome sequence of *Thermotoga maritima*." Nature 399:323-329).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagne H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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